K122791

JUN 04 2013

C. 510(K) SUMMARY

As required by 21 CFR 807.92

LYOPLANT® ONLAY

September 10, 2012

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Registration No.: 2916714

CONTACT: Denise R. Adams, Regulatory Affairs Specialist
610-984-9076 (phone)
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TRADE NAME: Lyoplant® Onlay

COMMON NAME: Dura Substitute

REGULATION: Dura Substitute

CLASS: II

PRODUCT CODE: GXQ

REGULATION: 882.5910

REVIEW PANEL: Neurology

INTENDED USE

Lyoplant Onlay is indicated as a dura substitute for the repair of the dura mater.

DEVICE DESCRIPTION

Lyoplant Onlay is a dura substitute implant made of pure collagen that is obtained from bovine pericardium and bovine split hide.

Lyoplant Onlay can be laid on the defect, or sutured depending upon surgeon preference. After implantation, it is gradually broken down enzymatically and is replaced by the body's own connective tissue. The appropriate size implant is selected depending on the area of application and is cut to size depending on the size of the defect. Lyoplant Onlay is supplied sterile and packaged as a single piece.

TECHNOLOGICAL CHARACTERISTICS

Lyoplant Onlay is available as single use, sterile, flexible sheets of pure collagen with adequate tear resistance and handling properties, impermeability to CSF, and satisfactory biocompatibility, thus fulfilling the requirements of a dura substitute as described in FDA's guidance document for Dura Substitute Devices.

PERFORMANCE DATA

Physical, mechanical, and biocompatibility testing have been performed on Lyoplant Onlay in accordance with the FDA guidance for industry for Dura Substitute Devices and has demonstrated the performance of Lyoplant Onlay as a dura substitute.

The following tests were conducted as recommended in the FDA guidance on Dura Substitute Devices:

- Device Thickness
- Tensile Strength
- Suture Retention Strength
- Burst Strength
- Shrink Temperature Range
- Surface Structure
- Delamination
- Chemical Characterization

The following biocompatibility testing was conducted in accordance with ISO 10993-1:

- Cytotoxicity
- Maximization Sensation Study
- Intracutaneous Study
- Systematic Toxicity
- Genotoxicity
- Hemolysis
- Muscle Implantation

Additionally, an animal study was conducted using thirty-four (34) pigs. The study was designed to investigate the safety and efficacy of Lyoplant® Onlay as a dura onlay graft in an in vivo model. Suturable DuraGen™ and autologous periosteum were used as control materials. Animals were sacrificed at one (1) month and six (6) months at which time gross and histologic assessment was made. Results of the study demonstrate superior handling of Lyoplant® Onlay and Suturable DuraGen™ over periosteum with a trend for better adhesion to dura and CSF tightness for Lyoplant® Onlay. Periosteum, which was sutured, had the highest intraoperative CSF tightness. Duraplasty time with periosteum was significantly higher (14.4±2.7 min) compared with Lyoplant® Onlay (2.8±0.8 min) or Suturable DuraGen™ (3.0±0.5 min). Tissue integration by fibroblast infiltration was observed after one (1) month for all devices. More adhesions between graft and cortex were observed with Suturable DuraGen™ compared with Lyoplant® Onlay and periosteum. No relevant adhesions between leptomeninges and Lyoplant® Onlay were observed and all devices showed comparable lymphocytic reaction of the brain. All devices were completely integrated after six (6) months. Lyoplant® Onlay and Suturable DuraGen™ showed a trend for an enhanced lymphocytic reaction of the brain parenchyma compared with periosteum. Implant rejection was not observed in any animals but several deaths occurred overall in the periosteum (n=3) and Suturable DuraGen™(n=4) cohorts.

Results of in vitro, in vivo, and biocompatibility testing demonstrate that Lyoplant Onlay performs in accordance with its specifications and is substantially equivalent in safety and effectiveness to the predicate devices Lyoplant ,Suturable DuraGen, and Durepair.

SUBSTANTIAL EQUIVALENCE

Lyoplant Onlay, Lyoplant, Suturable DuraGen, and Durepair have similar technological characteristics. These devices are available as single use, sterile, flexible sheets of pure collagen with adequate tear resistance and handling properties, impermeability to CSF, and satisfactory biocompatibility, thus fulfilling the requirements of a dura substitute.

The device modifications described in this premarket notification are substantially equivalent to the predicate device Lyoplant Dura Substitute cleared via K970851, Suturable DuraGen cleared via K043427, and Durepair cleared via K041000. Any technological differences between Lyoplant Onlay and the predicate devices do not raise new types of safety or effectiveness issues.

	Lyoplant Onlay (subject device)	**Lyoplant K970891 Aesculap**	**Suturable DuraGen K043247 Integra LifeSciences**	**Durepair K041000 Medtronic**
Indications for Use	Lyoplant Onlay is indicated as a dura substitute for the repair of the dura mater.	Intended as a dura mater substitute in neurological procedures for soft tissue reconstruction of damaged, impaired, or missing tissue.	Indicated as a dura substitute for the repair dura mater	Durepair® is indicated as a dura substitute for the repair of the dura mater.
Contra-indications	•Infected areas •Open cranial trauma •Open spina bifida •As a replacement for mechanically stressed connective tissue structures •As a substitute for parts in the arterial system or the cardiac wall •If there are known allergies to proteins of bovine origin	•Infected areas •Open cranial trauma •Open spina bifida •As a replacement for mechanically stressed connective tissue structures •As a substitute for parts in the arterial system or the cardiac wall	•For patients with a known history of hypersensitivity to bovine derived materials •Should be used with caution in infected regions	•Durepair is not designed, sold, or intended for use except as indicated. •Durepair should not used for patients with a known history of hypersensitivity to collagen products. •Durepair should be used with caution in regions where an infection exists.
Type of Collagen	bovine pericardium and bovine split hide	bovine pericardium	bovine Achilles tendon	bovine skin
Application	Onlay or suture	Suture	Onlay or suture	Onlay or suture
Sterilization	EtO	EtO	EtO	EtO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 4, 2013

Aesculap, Inc.
% Ms. Denise R. Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

Re: K122791
Trade/Device Name: Lyoplant® Onlay
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: April 29, 2013
Received: April 30, 2013

Dear Ms. Adams

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122791

Device Name: Lyoplant® Onlay

Indication for Use:

Lyoplant® Onlay is indicated as a dura substitute for the repair of the dura mater.

Prescription Use X or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H. Nguyen
2013.05.22 21:37:03 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)
510(k) Number K122791